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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/923,582      | 08/07/2001  | Robert A. Beach      | Q105                | 2712             |

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| EXAMINER |
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SINES, BRIAN J

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/923,582 | <b>Applicant(s)</b><br>BEACH ET AL. |  |
|                              | <b>Examiner</b><br>Brian J. Sines    | <b>Art Unit</b><br>1743             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10/7/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, this claim, in line 11, recites a “means” tuned to an optical absorption line of the analyte. Since the specific claim language used in defining this feature does not meet the 3-prong analysis for invoking 35 U.S.C. 112, sixth paragraph, it is unclear if applicant is intending to invoke 35 U.S.C. 112, sixth paragraph in claim interpretation (see MPEP § 2181). Does the applicant intend to invoke 35 U.S.C. 112, sixth paragraph for this feature? If so, the feature should be recited using the appropriate claim language.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

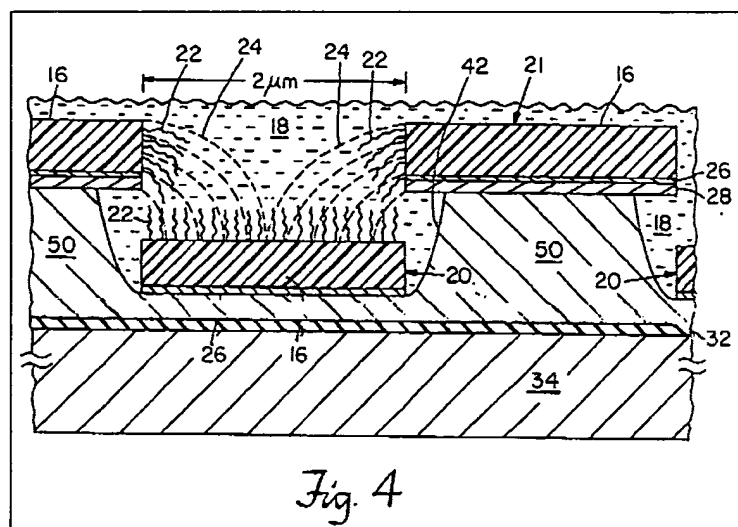
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

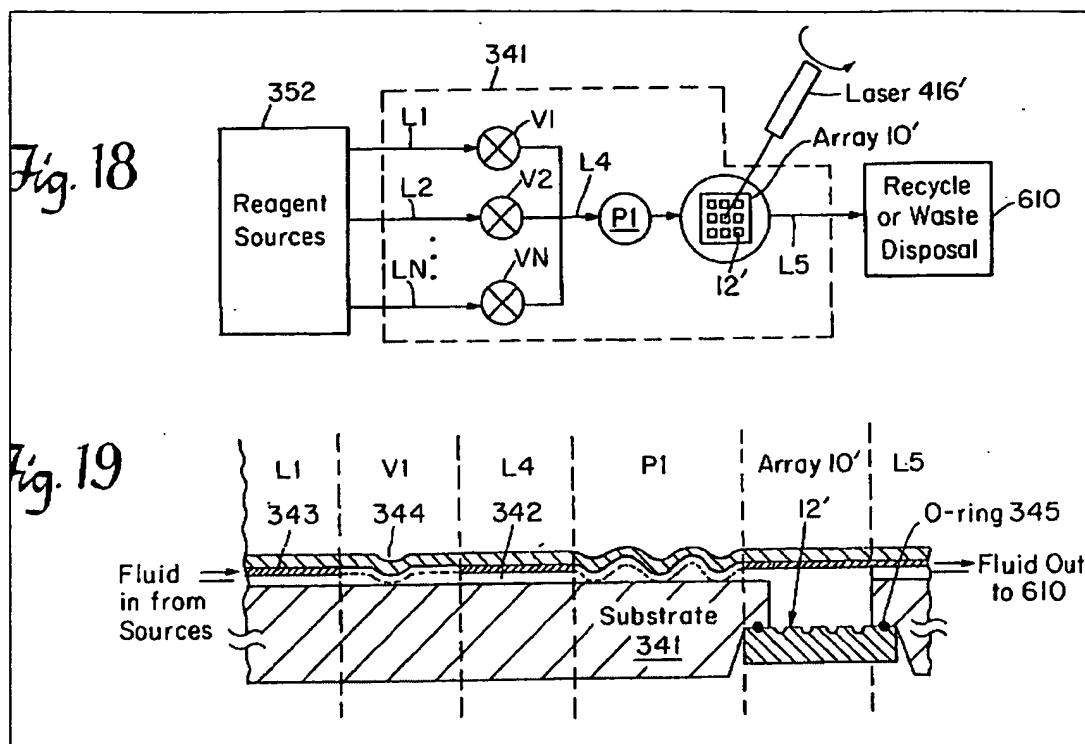
1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (U.S. Pat. No. 5,653,939 A) (hereinafter “Hollis”) in view of Wainright et al. (U.S. Pat. No. 6,306,273 B1) (hereinafter “Wainright”).

Regarding claim 5, Hollis teaches an apparatus comprising: an integrated microfluidic peristaltic pump (P1); a plurality of analysis chambers (wells 42 formed in each test site 12' contained in array 10) in communication with the pump; and a plurality of analysis devices (i.e., a micromechanical resonator, surface acoustic or electromagnetic wave detector, or a monolithically integrated charge-coupled device (CCD), etc.), which test a fluid contained within the analysis chambers for an analyte (see col. 4, line 15 – col. 15, line 51; figures 1 – 6, 18 & 19).





Hollis is silent to specifically teaching the incorporation of an integrated LED. Hollis does teach the incorporation of an integrated optical detector, such as a monolithically integrated charge-coupled device (CCD) (see col. 8, lines 59 – 67). Hollis does teach the incorporation of a laser light source (416') for laser scanning of the test sites (see col. 14, lines 33 – 50). Wainright does teach the use of LED and laser diode light sources with a microfluidic analysis system. Wainright also teaches that the detection may be performed using laser scanned excitation and CCD camera detection (see col. 21, line 56 – col. 22, line 24). Therefore, a person of ordinary skill in the art, as evidenced by Wainright, would have recognized the suitability of incorporating an integrated LED with a microfluidic analysis system for the same intended purpose of facilitating effective sample processing and analysis (see MPEP § 2144.07). Furthermore, these light emission and detection systems are considered functionally equivalent (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one

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equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). In addition, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed or taught in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (see MPEP § 2144.04). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an integrated LED with the disclosed analytical detection system in order to facilitate effective sample processing and analysis.

Regarding the recitation that the integrated LED and optical detector further comprise means tuned to an optical wavelength absorption line of an analyte, it is deemed obvious to a person of ordinary skill in the art to provide tuning means, such as for an appropriate light wavelength emission, so that the apparatus would function properly as intended in order to effectively detect the target analyte.

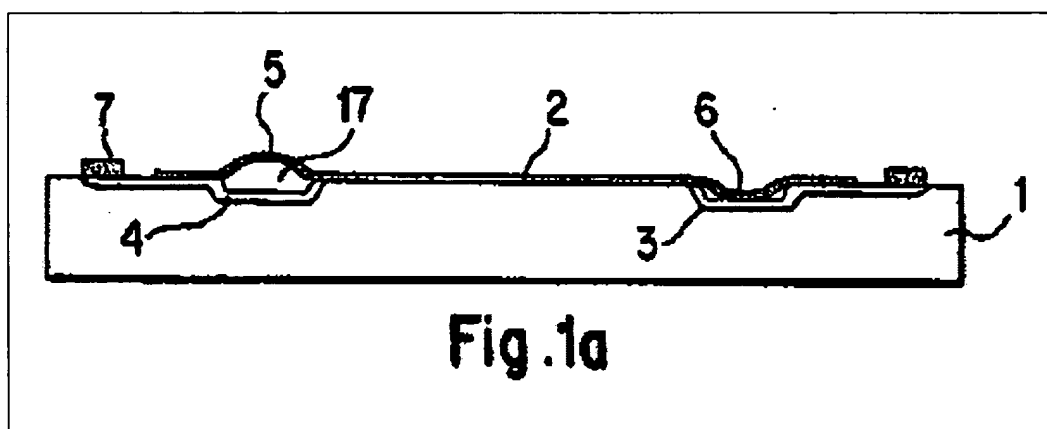
2. Claims 6 – 8, 11 – 13, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis in view of Lisec et al. (U.S. Pat. No. 6,655,923 B1) (hereinafter “Lisec”).

Regarding claims 6, 7 and 11 – 13, Hollis teaches an apparatus comprising: an integrated microfluidic peristaltic pump (P1); a plurality of analysis chambers (wells 42 formed in each test site 12' contained in array 10) in communication with the pump; and a plurality of analysis devices (i.e., a micromechanical resonator, surface acoustic or electromagnetic wave detector, or a monolithically integrated charge-coupled device (CCD), etc.), which test a fluid contained within the analysis chambers for an analyte; (see col. 4, line 15 – col. 15, line 51; figures 1 – 6,

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18 & 19). Hollis does not specifically teach the incorporation of a micropump comprising the characteristics as recited.

Lisec teaches a micropump apparatus comprising: an electrodeformable membrane (denoted by 2, 5 and 6); a fixed substrate (1); a microchannel or cavity (e.g., the volume indicated by numeral 17); an electrode structure (3 and 4); and associated pillar-shaped contact pads (7) (see col. 4, lines 35 – 67; figures 1a, 5, 6a and 6b).



Therefore, a person of ordinary skill in the art would have recognized the suitability of incorporating the micropumps disclosed by Lisec with a microfluidic analysis system for the same intended purpose of facilitating effective fluid transport and therefore sample processing and analysis (see MPEP § 2144.07). Furthermore, as discussed above, both Hollis and Lisec disclose the use of micropumps with analytical microfluidic devices, which are considered functionally equivalent (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the disclosed

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micropump with the analytical detection system in order to facilitate effective sample processing and analysis.

Regarding claim 8, Lisec teaches that an electrical voltage is applied between the selected electrodes and the membrane in order to operate the pump (see col. 5, lines 45 – 60). Hence, it is inherently anticipated that a drive circuit is used in enabling this function (see MPEP § 2112).

3. Claims 9, 10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis and Lisec, as applied to the claims above, and further in view of Purdy (U.S. Pat. No. 6,177,057 B1) (hereinafter “Purdy”).

Regarding claims 9, 10, 14 and 15, neither Hollis nor Lisec specifically teach the incorporation of gallium nitride materials for use as an electrodeformable membrane. As evidenced by Purdy, the use of gallium nitride materials in the fabrication of microfluidic devices are well known in the art. Gallium nitride materials are recognized to have high mechanical stability and a large piezoelectric constant (see col. 1, lines 10 – 19). These material properties are desirable in a material to be used as an electrodeformable membrane. The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). In addition, the rationale to support an obviousness rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle (see MPEP § 2144.02). Thus, a person of ordinary skill in the art would have recognized the suitability of using gallium nitride materials in an application involving electromechanical deformation, such as for an electrodeformable membrane. Therefore, it would have been obvious to a person of



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ordinary skill in the art to incorporate the use of gallium nitride materials as an electrodeformable membrane with the disclosed apparatus as claimed.

***Response to Arguments***

Applicant's arguments with respect to the pending claims have been considered, but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D., whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian J. Sines". The signature is stylized with a large, looping initial "B" and a long, sweeping underline.